AUG 0 1 2002

K021995

510(k) Summary

Specialty Drive Technologies, Inc.'s Escape Control Module

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Specialty Control Technologies, Inc.
509 Pleasant Hill Church Rd.
Winder, GA 30680
Phone: 770 363-7398
Fax: 770 586-0917

Contact Person: Scott Kersey

Date Prepared: June 17, 2002

Name of Device and Name/Address Of Sponsor

Escape Control Module
Specialty Control Technologies, Inc.
509 Pleasant Hill Church Rd.
Winder, GA 30680
Phone: 770 363-7398
Fax: 770 586-0917

Common or Usual Name

Escape Control Module

Classification Name

Power Wheelchair Control Unit

Predicate Devices

The Escape Control Module is substantially equivalent to Dynamic Systems PHC-2 and PHC-3, Adaptive Switch Laboratories Inc.'s ASL Head Array, Invacare's Sip and Puff head array and Invacare's Remote Joystick.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 01 2002

Specialty Drives Technologies, Inc.
Scott Kersey
509 Pleasant Hill Church Road
Winder, Georgia 30680

Re: K021995
Trade Name: Escape Control Module
Regulation Number: 890.3860
Regulation Name: Wheelchair, powered (accessory)
Regulatory Class: II
Product Code: ITI
Dated: June 17, 2002
Received: June 18, 2002

Dear Mr. Kersey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K021995

Device Name: _____

Indications for Use: The Escape Control Module is a non-contact, fully proportional, head movement commanded driving control intended to provide mobility to persons restricted to a seated position while operating a variety of powered wheelchairs.

PLEASE DO NOT WRITE BELOW THIS LINE
(CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-Counter Use ✓
(Per 21 CFR 801.109) (Optional Format 1-2-96)

for Mark N Milhoan

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K021995

(Division Sign-Off)
Division of General Restorative Devices

510(k) Number _____